

K974784



FEB 24 1998

510(k) Summary

SCIENTIFIC CORPORATION

- (a) (1) **Submitter's name, address**
 AVL Scientific Corporation
 33 Mansell Court
 Roswell, GA 30076
- Contact Person**
 Randy Byrd
 Quality Assurance Manager
 (770) 587-4040 x 631
- Date of preparation of this summary:** 18 December 1997
- (2) **Device trade or proprietary name:** AVL OPTI Critical Care Analyzer
- Device common or usual name or classification name**

pH, Blood Gas, Electrolyte, hemoglobin and oxygen saturation analyzer

PRODUCT NOMENCLATURE	CLASSIFICATION		
	NUMBER	CLASS	PANEL
ELECTRODE, ION-SPECIFIC, POTASSIUM	75 CEM	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, SODIUM	75 JGS	II	CHEMISTRY
ELECTRODE, BLOOD PH	75 CHL	II	CHEMISTRY
BLOOD GASES/PH	75 CHL	II	CHEMISTRY
HEMOGLOBINOMETER, AUTOMATED	81 GKR	II	HEMATOLOGY
OXIMETER, WHOLE BLOOD	81 GLY	II	HEMATOLOGY

(3) Substantial Equivalence

The AVL OPTI is substantially equivalent in function, safety and efficacy to a number of currently marketed devices known as 'Combi Analyzers' and 'Point of Care' analyzers, Specifically: NOVA Biomedical STAT 5 [K874832], Chiron 865 [K946206], AVL 995 [K895317], SenDx 100 [954482], Diametrics IRMA [945240], I-STAT 200 [940918], as well as electrolyte analyzers such as AVL 9181 [972763] and IL 943 Flame Photometer [K823480]. The OPTI Critical Care Analyzer is an improved design of the AVL OPTI 1 pH/Blood Gas Analyzer [K944089 and K961161].

(4) Description of the new device

The AVL OPTI Critical Care Analyzer is a small [4.9 x 14.3 x 9.8 in, 10 lbs], instrument using optical fluorescence for the measurement of pH, PCO₂, PO₂, sodium and potassium of whole blood, plasma or serum as appropriate. In addition, it uses optical reflectance for the measurement of total hemoglobin and oxygen saturation. A disposable, single-use cassette containing six optical fluorescence sensors is packaged in a sealed foil pouch which bears a bar-coded label with calibration and identification information. The OPTI can perform up to 7 tests on a single sample, determined by the type of disposable cassette used.

Cassette Type	Analytes
B	pH, PCO ₂ , PO ₂ , ctHb, SO ₂
E	pH, PCO ₂ , PO ₂ , ctHb, SO ₂ , Na ⁺ , K ⁺

(5) Intended use of the device

The AVL OPTI Critical Care Analyzer is intended to be used for the measurement of pH, PCO_2 , PO_2 , sodium, potassium, total hemoglobin content and oxygen saturation in samples of whole blood, serum, and plasma in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

(6) Technological characteristics of the device.**Principles of Measurement**

The OPTI Critical Analyzer uses fluorescence optode technology similar to that used in commercially available products since late 1983 and is unchanged in principle of operation from the originally submitted 510(k) for this device. Additional parameters, Sodium and Potassium, are measured by fluorescence and measurement of total Hemoglobin (ctHb) and oxygen saturation (SO_2) is accomplished by optical reflectance.

Calibration

A disposable, single-use cassette contains all the elements needed for calibration, QC sample measurement, patient sample measurement and waste containment. Calibration verification is performed with each cassette immediately prior to use. No other calibration is required for the usual operation of this device for the measurement of pH, PCO_2 , PO_2 , Na^+ , K^+ , tHb and SO_2 .

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

The AVL OPTI Critical Care Analyzer has been tested and found to comply with EN 50081-1, FCC Class B, EN 50081-2 and IEC 1010-1.

Precision

Typical Within-Run (S_{wr}), Between-Day (S_{dd}) and Total (ST) precision were determined from two runs per day with 2 replicates per run for 20 days on two AVL OPTI instruments using samples plasma, reduced bovine hemoglobin solution and three levels of aqueous quality control solution.

Linearity

Wherever possible, linearity for the OPTI measurement has been established against reference materials or methods. Linearity for pH of whole blood is established by measurement of blood specimens which were tonometered to various CO_2 values, and measured on an AVL 995 pH/Blood Gas Analyzer standardized to N.I.S.T. traceable pH buffers, and on three OPTI Critical Care Analyzers.

Interferences¹

Representative samples taken the published guidelines for evaluation of interference substances and identified from literature were evaluated.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

Clinical testing was conducted to demonstrate the correlation of AVL OPTI Critical Care Analyzer to predicate devices in a clinical setting, operated by personnel trained to perform and report these analyses. Specimens analyzed in these tests were remnant from patient specimens of both whole blood and serum collected for routing analysis on existing instrumentation.

In all evaluations, there was no significant difference in mean values ($P < 0.05$) obtained on measurement by the AVL OPTI.

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Analysis of the comparative measurement presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and non-clinical trials demonstrates that the AVL OPTI Critical Care Analyzer with the additional analytes, sodium, potassium, total hemoglobin and oxygen saturation, is safe and effective, and equivalent to those predicate devices to which it is compared.

¹ NCCLS. Interference Testing in Clinical Chemistry; Proposed Guideline. NCCLS Document EP7-P. NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania 19085, 1986.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 24 1998

Randy Byrd
Quality Assurance Manager
AVL Scientific Corporation
33 Mansell Court
Roswell, Georgia 30076

Re: K974784
AVL OPTI Critical Care Analyzer
Regulatory Class: II
Product Code: CEM, CHL, GKR, GLY, JGS
Dated: December 18, 1997
Received: December 22, 1997

Dear Mr. Byrd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

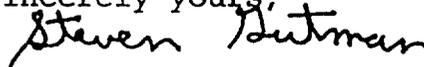
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: AVL OPTI Critical Care Analyzer

The AVL OPTI Critical Care Analyzer intended to be used for the measurement of pH, PCO_2 , PO_2 , ctHb, SO_2 , Na^+ and K^+ in whole blood, serum and plasma as appropriate by minimally trained personnel qualified to perform and to report these values in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

For Professional Use Only
For *In Vitro* Diagnostic Use

Indications for Use^{1,2}**pH**

The pH value of the blood may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

- primary bicarbonate deficit metabolic acidosis
- primary bicarbonate excess metabolic alkalosis
- primary hypoventilation respiratory acidosis
- primary hyperventilation respiratory alkalosis

An increase in blood, serum or plasma pH (*alkalemia*) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2 due to hyperventilation.

A decrease of pH value (*acidemia*) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+ -ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute, as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic, as the result of obstructive or restrictive respiratory diseases.

The composition of serous body fluids: pleural, pericardial, ascitic and cerebrospinal fluid, is similar to serum and plasma in electrolyte content and pH. The AVL OPTI may be used for the analysis of these fluids, limited to a pH in

¹ Tietz, Norbert W., Ed., Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p.436.

² Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1994) pp.1354-1360,2180-2206.

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the range between 6.8 and 7.7, as long as care is taken to ensure the specimen to be analyzed is clear of fibrin clots or other debris which may block the sample transport in the cassette.

Pleural fluid³

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions. Patients with pneumonia may develop effusions when the infectious process extends to the visceral pleura, causing exudation of fluid into the pleural space. Fluids are divided into potentially benign and complicated effusions on the basis of pH. Fluids with a pH greater than 7.30 resolve spontaneously, whereas a pH less than 7.20 is an indication of tube drainage.

PCO₂

The PCO₂ value of arterial blood is used to assess how well the body eliminates carbon dioxide in relation to the metabolic rate of CO₂ production.

An arterial PCO₂ below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO₂ above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

PO₂

The PO₂ value of arterial blood has become the primary tool for the evaluation of arterial oxygenation status. Values below the normal arterial PO₂ (arterial *hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired O₂ content). Generally, PO₂ levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO₂ provides a 97 % saturation level, and a level greater than 100 % cannot be achieved.

Sodium

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular

³ Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, analysis and correlation, 2nd Ed. (St. Louis: C.V. Mosby Co. 1989) p 590-591.

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excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adreocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance; infusion therapies; vomiting; diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Potassium

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea and hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

total Hemoglobin concentration (ctHb)

The hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram/dL of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than the others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid. Decreases in the amount of hemoglobin can come about as a result of a decreased concentration of hemoglobin in the erythrocytes, or a decreased number of erythrocytes that contain a normal concentration of hemoglobin.

Decreased levels are found in anemia states, hyperthyroidism, severe hemorrhage and hemolytic reactions due to transfusions of incompatible blood, reaction to chemical, infectious and physical agents as well as various systemic diseases. Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

ctHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

ctHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Oxygen Saturation ($SO_2\%$)

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin (O_2Hb). The amount of oxyhemoglobin, expressed as a fraction of the total available hemoglobin is termed, hemoglobin oxygen saturation (SO_2). The largest portion (about 98%) of blood oxygen content is the oxygen bound to hemoglobin. The reference interval for arterial blood from healthy adults is typically 94 to 98%⁴. Decrease in SO_2 below the critical level necessary for tissue oxygen saturation is a grave clinical situation. Low oxygen saturation may be caused by many of the same factors responsible for arterial *hypoxemia*, as well as from unusually large amounts of non-functional hemoglobins, high concentrations of deoxyhemoglobin, chemically altered hemoglobin or factors affecting the affinity of hemoglobin for oxygen, including: temperature, pH, PCO_2 , 2,3-DPG concentration and type of hemoglobin.⁵

⁴ Siggaard-Andersen O, Durst RA, Maas AHJ. IFCC/IUPAC approved recommendation (1984) on physicochemical quantities and units in clinical chemistry. *J Clin Chem Clin Biochem.* 25:369-391, 1987.

⁵ Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1994) pp.1354-1360,2180-2206.

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[Signature]
James Colaghan Reviewed

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

[Signature]
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 12974784